

- 1 1. (Original) An oral solid composition of nateglinide comprising:
 - 2 a) nateglinide or pharmaceutically acceptable salts thereof; and
 - 3 b) at least one pharmaceutically acceptable surfactant,
- 1 2. (Original) The oral solid composition of claim 1, wherein the nateglinide comprises
2 an amount of from about 5% w/w to about 70% w/w of the composition.
- 1 3. (Original) The oral solid composition of claim 1, wherein the surfactant comprises
2 one or more of anionic, nonionic, cationic, and mixtures thereof.
- 1 4. (Original) The oral solid composition of claim 3, wherein the anionic surfactants
2 comprises one or more of sodium lauryl sulphate, potassium dodecyl sulphonate, sodium
3 dodecyl benzene sulphonate, sodium salt of lauryl polyoxyethylene sulphate, lauryl
4 polyethylene oxide sulfonate, dioctyl ester of sodium sulphosuccinic acid or sodium lauryl
5 sulphonate, and mixtures thereof.
- 1 5. (Original) The oral solid composition of claim 4, wherein the surfactant is sodium
2 lauryl sulphate.
- 1 6. (Original) The oral solid composition of claim 3, wherein the nonionic surfactants
2 comprises one or more of polysorbate 80, nonyl phenol polyoxyethylene ether, tridecyl
3 alcohol polyoxyethylene ether, dodecyl mercaptan polyoxyethylene thioether, the lauric ester
4 of polyethylene glycol, the lauric ester of sorbitan polyoxyethylene ether or tertiary alkyl
5 amine oxide, and mixtures thereof.
- 1 7. (Original) The oral solid composition of claim 6, wherein the surfactant is polysorbate
2 80.
- 1 8. (Original) The oral solid composition of claim 3, wherein the cationic surfactants
2 comprises one or more of distearyl dimethyl ammonium chloride, stearyl dimethyl benzyl
3 ammonium chloride, stearyl trimethyl ammonium chloride, coco dimethyl benzyl ammonium
4 chloride, dicoco dimethyl ammonium chloride, cetyl pyridinium chloride, cetyl trimethyl
5 ammonium bromide, stearyl amine salts that are soluble in water such as stearyl amine acetate
6 and stearyl amine hydrochloride, stearyl dimethyl amine hydrochloride, distearyl amine
7 hydrochloride, alkyl phenoxyethoxyethyl dimethyl ammonium chloride, decyl pyridinium

8 bromide, pyridinium chloride derivative of the acetyl amino ethyl esters of lauric acid, lauryl
9 trimethyl ammonium chloride, decyl amine acetate, lauryl dimethyl ethyl ammonium
10 chloride, the lactic acid and citric acid and other acid salts of stearyl-1-amidoimidazoline with
11 methyl chloride, benzyl chloride, chloroacetic acid and similar compounds, and mixtures
12 thereof.

1 9. (Original) The oral solid composition of claim 1, wherein the surfactant comprises an
2 amount of from about 0.5% w/w to about 10% w/w of the composition.

1 10. (Original) The oral solid composition of claim 1, wherein the composition further
2 comprises one or more pharmaceutically acceptable excipients comprising fillers, binders,
3 disintegrants, lubricants, glidants, coloring agents, flavoring agents, and coatings.

1 11. (Original) The oral solid composition of claim 10, wherein the filler comprises one or
2 more of corn starch, lactose, white sugar, sucrose, sugar compressible, sugar confectioners,
3 glucose, sorbitol, calcium carbonate, calcium phosphate-dibasic, calcium phosphate-tribasic,
4 calcium sulfate, microcrystalline cellulose, silicified microcrystalline cellulose, cellulose
5 powdered, dextrates, dextrins, dextrose, fructose, kaolin, lactitol, mannitol, sorbitol, starch,
6 starch pregelatinized, sucrose, and mixtures thereof.

1 12 – 13 (Cancelled)

1 14. (Original) The oral solid composition of claim 10, wherein the binder comprises one
2 or more of methyl cellulose, hydroxypropyl cellulose, polyvinylpyrrolidone, gelatin, gum
3 arabic, ethyl cellulose, polyvinyl alcohol, pullulan, pregelatinized starch, agar, tragacanth,
4 sodium alginate, propylene glycol, and mixtures thereof.

1 15. (Cancelled).

1 16. (Original) The oral solid composition of claim 10, wherein the disintegrant comprises
2 one or more of starch, croscarmellose sodium, crospovidone, sodium starch glycolate, and
3 mixtures thereof.

1 17. (Cancelled)

1 18. (Original) The oral solid composition of claim 10, wherein the lubricant comprises
2 one or more of colloidal anhydrous silica, stearic acid, magnesium stearate, calcium stearate,
3 talc, hydrogenated castor oil, sucrose esters of fatty acids, microcrystalline wax, yellow
4 beeswax, white beeswax, and mixtures thereof.

1 19. (Cancelled)

1 20. (Original) The oral solid composition of claim 1, further comprising at least one other
2 anti-diabetic compound.

1 21. (Original) The oral solid composition of claim 20, wherein the antidiabetic compound
2 comprises glitazones, sulfonyl urea derivatives and metformin, either in free form or in form
3 of a pharmaceutically acceptable salt thereof.

1 22. (Original) The oral solid composition of claim 1, wherein the composition comprises
2 one or more of powder, tablets, granules, pellets, spheroids, caplets and capsules.

1 23 - 32. (Cancelled)

1 33. (Original) A process for the preparation of a pharmaceutical composition of
2 nateglinide, the process comprising the steps of:

3 i. blending nateglinide or pharmaceutically acceptable salts thereof,
4 surfactant and one or more pharmaceutically acceptable excipients;
5 and;

6 ii. processing into a solid dosage form.

1 34. (Original) The process of claim 33, wherein the blend of step a) is granulated.

1 35. (Original) The process of claim 34, wherein the granulation is carried out by a wet
2 granulation or a dry granulation technique.

1 36. (Cancelled)

1 37. (Currently Amended) The process of claim 36 35, wherein the wet granulation is
2 carried out using a granulating fluid comprising one or more of methylene chloride, isopropyl
3 alcohol, acetone, methanol, ethanol, water, and mixtures thereof.

1 38. (Cancelled)

1 39. (Currently Amended) The process of claim 38 35, wherein the dry granulation is
2 carried out by slugging or roller compaction.

1 40. (Cancelled)

1 41. (Original) The process of claim 33, further comprising mixing at least one other
2 antidiabetic compound.

1 42. (Original) The process of claim 41, wherein the antidiabetic compound comprises one
2 or more of glitazones, sulfonyl urea derivatives and metformin, either in free form or in form
3 of a pharmaceutically acceptable salt.

1 43. (Original) The process of claim 33, wherein the dosage form comprises one or more
2 of powder, tablets, granules, pellets, spheroids, caplets and capsules.

1 45 - 46 (Cancelled)

1 47. (Original) A process for preparation of oral tablets of nateglinide, the process
2 comprising blending nateglinide, surfactant, filler, disintegrant, binder and lubricant; and
3 compressing.

1 48. (Original) A method for the prevention or treatment of metabolic disorders, type 2
2 diabetes mellitus, or a disease or condition associated with diabetes mellitus, the method
3 comprising administering to a patient in need thereof a pharmaceutical composition
4 comprising nateglinide or pharmaceutically acceptable salts thereof; and at least one
5 pharmaceutically acceptable surfactant.